

In re Application of: MALONEK et al.  
Serial No.: 09/849,637  
Filed: May 4, 2001  
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko  
Group Art Unit: 3762  
Attorney Docket: IMP031.228776

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 5-33, 36-41, 43-48, 50-61, 63-78, 80, 82, 84 and 86-94 are in this Application. Claims 5-18, 20-33, 36-40, 45/(5-18, 20-33, 36-40), 46-48, 50-61 and 63-73 have been withdrawn from consideration. Claims 19, 41, 43-45, 74-78, 80, 82, 84, 86-94 have been rejected. Claims 19, 41-44, 45/(19 and 41-44) and 74-94 have been rejected under 35 U.S.C. § 112. Claims 41, 43, 44, 45/(41, 43, 44), 74, 75, 78, 87, 91 and 94 have been rejected under 35 U.S.C. § 102(b). Claims 19, 45/19, 76, 77, 80, 82, 84, 86, 88-90, 92, and 93 have been rejected under 35 U.S.C. § 103(a). Claims 1-4, 34-35, 42, 49, 62, 79 83 and 85 have been canceled in a previous response. Claims 43, 44, 77, and 86 have been amended herewith. New claims 95-103 have been added herewith.

### **Information Disclosure Statement**

The Examiner notes that the disclosure statement filed 2/2/07 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance of each patent listed that is not in the English language.

Applicant notes that the disclosure of listed Patent Publication DE2613072 is also published as US Patent 4,773,433. The Examiner's attention is directed to the attached US Patent 4,773,433 providing an explanation of DE2613072 previously missing from the IDS filed on 2/2/07.

Applicants hereby request that the Examiner consider the information referred to therein.

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**Amendments To The Claims**

**35 U.S.C. § 112 Rejections**

Claims 19, 41-44, 45/(19 and 41-44) and 74-94 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner maintains that the claims contain subject matter which was not described in the specification in such a way as to enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More particularly the Examiner maintains:

(1) that the subject matter not disclosed is how to make a unitary/signal electrode having a capacitance greater than 300 microfarads and less than 3000 microfarads, in combination with other elements in the claims, and

(2) that one skilled in the art could not practice/make the invention without undue experimentation to arrive at an electrode with a capacitance of 300-3000 microfarads.

Applicants respectfully traverse the above rejection.

To be enabling under 35 U.S.C. §112, a patent specification must sufficiently disclose an invention to enable those skilled in the art to make and use it. Not every step need be set forth in the specification, and the specification need not disclose what is well known in that art. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ481 (Fed. Cir. 1984).

The Examiner has characterized the "amount of direction" provided by the present application as "minimal". Applicants respectfully submit that the Examiner is not considering that there was abundant knowledge available to one skilled in the art as of November 1999 regarding the preparation of electrodes having a desired

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capacitance such that an art-skilled individual would have been able to practice the invention without undue experimentation.

The Examiner's attention is directed to the Supplemental Declaration Under 37 C.F.R. §1.132 of Shawn Moaddeb (the "Declaration") submitted on January 31, 2007. Mr. Moaddeb is an expert in the field of leads and electrodes, and he has extensive experience in the field of designing and manufacturing leads. He indicates what he would expect an art-skilled person to know or have access to how an electrode can be manufactured to have a capacitance within a desired range, such as within the range of from greater than 300 microfarads to less than 3000 microfarads. Mr. Moaddeb also expressly states in item 55 of the Declaration that "in November 1999 one skilled in the art with the Application before him or her would readily have been able to produce an electrode having a capacitance of from 300 to about 3000 microfarads using techniques known in the art. Moreover, that art-skilled individual would have been able to produce that electrode without undue experimentation."

In the present and prior Office Actions the Examiner posed or referred to several questions, which it is believed are well answered in the Declaration. With regard to how to make an electrode with a capacitance between 300-3000 microfarads, Applicants refer the Examiner to items 40 to 54 in the Declaration. In item 40 to 54 in the Declaration, Mr. Moaddeb demonstrates an example how one skilled in the art can prepare a lead according to the invention after reading the Application without undue experimentation.

As is stated in the Declaration, it should be clear that other methods and materials are known and available. In one example pointed out by the Examiner in the previous office action and disclosed in Botvidsson et al. (4611604), there is a lead diameter of 3 mm, an electrode length of 0.5 mm and use of a capacitance of 10-100 mF per centimeter squared. Using 10 mF and the surface area of the electrode provides a capacitance of approximately 470 microfarads. A range of materials that

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can be used are described for example in column 3, lines 39-46 in Botvidsson. This further supports the Declaration that the technology in general was well known.

In reference to the Examiner's statement regarding Applicants argument on page 16 of the reply dated 6/10/05 where the Applicants have stated that the same materials used by the Applicants (titanium nitride, iridium oxide) at most have a capacitance of 150 microfarads. Applicants refer the Examiner to item 14 in the Declaration. In item 14, Mr. Moaddeb clearly states "the larger the plate area, the larger the capacitance". As is explained in Applicants arguments on page 16 of the reply dated 6/10/05, for pacing electrodes it is important to keep the total geometrical surface area of a pacing electrode small. As such the capacitance that can be achieved for pacing electrodes is limited, e.g. typically not more than 140 microfarads. Increasing the length of the electrode as is described in Applicants invention serves to increase the capacitance that can be achieved.

Regarding the Examiners statement, that the claims are very broad, Applicants assert that the whole range of the claim is supported by the Application. Support for the whole range of the claims is affirmed by the Declaration. Applicants have currently amended independent claim 43 to further the case to allowance. Currently amended claim 43 includes the limitation that the at least one signal delivery electrode is in the form of a flexible circumferential element positioned around the lead, having a diameter less than 1.5 mm.

Applicants respectfully submit that, consistent with the Declaration and in light of the present amendment to independent claim 43, the present claims are fully enabled and that the rejection under 35 U.S.C. §112, first paragraph, for lack of enablement should be withdrawn.

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Claim 86 has been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Examiner has stated that claim 86 is incomplete for omitting essential structural relationships to any other element in claim 43. Applicants have currently amended claim 86 to include the structural relationship of at least one sensing electrode flanking said at least one signal delivery electrode and the relationship of suitable circuitry for determining a stimulus to be applied by said at least one signal delivery electrode.

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35 U.S.C. § 102 Rejections

Claims 41, 43, 44, 45/(41, 43, 44), 74, 75, 78, 87, 91 and 94 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Botvidsson et al. (4611604). The Examiner has stated that Botvidsson discloses a lead diameter of 3 mm, an electrode length of 0.5 mm, and the use of a capacitance between 10-100 mF per centimeter squared. Using 10 mF and the surface area of the electrodes, provides a capacitance of approximately 470 microFarads. Applicants notes, that Botvidsson teaches a ring electrode having a length that is a minor fraction of 5mm so as to hardly change the mechanical properties of the highly flexible cable as is described in column 3, lines 22 to 28 in Botvidsson. In order to achieve a capacitance of 470 microfarads with Applicants electrode having a diameter suitable for coronary vessels of, for example less than 1.5 mm as is stated in Applicants' currently amended independent claim 43, Botvidsson would have to significantly increase the length of his electrode, e.g. increase by at least a factor of 2. Botvidsson teaches a rigid ring electrode having a minimal length so that the high flexibility of his cable is largely guaranteed even in the area of the electrode as is stated in column 2, lines 39-44 and in column 3, lines 25-29. Botvidsson clearly teaches away from reducing the diameter of the ring at the expense of lengthening his ring electrode.

Claims 41, 44, 45/(41, 43, 44), 74, 75, 78, 87, 91 and 94 depend directly and/or indirectly from currently amended independent claim 43 and therefore include the limitations of currently amended independent claim 43. Applicants respectfully assert that claims 41, 44, 45/(41, 43, 44), 74, 75, 78, 87, 91 and 94 as amended are not anticipated by Bodvidsson and respectfully request that the Examiner withdraw his rejections to claims 41, 44, 45/(41, 43, 44), 74, 75, 78, 87, 91 and 94.

Claims 41, 43, 44, 45/(41, 43, 44), 87, 91 and 94 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Mund et al. (4603704). Mund discloses an example of a hemishpherical electrode head having a diameter of 2mm. In Applicants'

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currently amended independent claim 43, the electrode is limited to an electrode in the form of a flexible circumferential element positioned around the lead having a diameter less than 1.5 mm.

Mund does not disclose an electrode in the form of a flexible circumferential element positioned around the lead having a diameter less than 1.5 mm as is required by Applicants' currently amended independent claim 43 and therefore is not anticipated by Mund. Mund's electrode is rigid and therefore can not be lengthened.

Claims 41, 44, 45/(41, 43, 44), 87, 91 and 94 depend directly and/or indirectly from currently amended independent claim 43 and therefore include the limitations of currently amended independent claim 43. Applicants respectfully assert that claims 41, 43, 44, 45/(41, 43, 44), 87, 91 and 94 as amended are not anticipated by Mund and respectfully request that the Examiner withdraw his rejections to claims 41, 43, 44, 45/(41, 43, 44), 87, 91 and 94.

35 U.S.C. § 103 Rejections

Claims 19, 45/19, 76, 77, 80, 82, 84, 86, 88-90, 92, and 93 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Botvidsson or Mund. The Examiner states in his rejection that it would have been obvious to any one having ordinary skill in the art at the time the invention was made to include in the heart leads as taught by Botvidsson or Mund, the different materials for the electrode, the lead diameter smaller than 1.5/1.2 mm, the electrode longer than a pacing electrode and shorter than a defibrillation electrode, and the sensing electrode and second connections means.

Applicants respectfully assert that it would not be obvious to any one having ordinary skill in the art at the time the invention was made to include in the heart leads as taught by Botvidsson or Mund at least the lead diameter smaller than 1.5/1.2 for with a signal electrode in the form of a flexible circumferential element positioned

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around the lead having a capacitance between 300-3000 microfarads as is required by Applicants' currently amended independent claim 43 from which claims 19, 45/19, 76, 77, 80, 82, 84, 86, 88-90, 92, and 93 depend. Decreasing Botvidsson's ring electrode from a diameter of 3 mm to a diameter 1.5/1.2 mm would require lengthening the size of the electrode to obtain the required capacitance. Botvidsson clearly teaches away from increasing the length of his electrode as described hereinabove. Botvidsson's electrode is rigid. Increasing the length of Botvidsson's ring electrode would stiffen the otherwise extremely flexible electrical cable which as stated by Botvidsson is undersirable. Botvidsson discusses pacing that requires a high current concentration. As such Botvidsson teaches away from lengthening the electrode since this would serve to decrease the current concentration.

Applicants' currently amended independent claim 43 from which claims 19, 45/19, 76, 77, 80, 82, 84, 86, 88-90, 92, and 93 depend, require a signal delivery electrode in the form of a flexible circumferential element positioned around the lead. Mund's electrode is a hemispherical electrode at the tip of the lead. Mund discusses pacing that requires a high current concentration. As such Mund teaches away from lengthening the electrode since this would serve to decrease the current concentration.

Applicants have added new claims 95-103. Applicant asserts that no new matter has been added by new claims 95-103. Claim 95 adds the limitation that the at least one signal delivery electrode is formed by a coil spirally wound around the lead. Claim 96 adds the limitation that the at least one signal delivery electrode is formed by a mesh of wires. Claim 97 adds the limitation the at least one sensing electrode includes pairs of sensing electrodes. Claim 98 adds the limitation that a pair of sensing electrodes from the pairs of sensing electrodes is positioned on each side of the at least one signal delivery electrode. Claim 99 adds the limitation that the pairs of sensing electrodes are positioned on the lead in a position so that they can sense a local electrical activity of cardiac muscle under the at least one signal delivery electrode.



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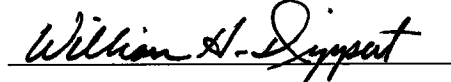
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Claim 100 adds the limitation of a soft rounded tip at the distal end. Claim 101 adds the limitation that signal delivery electrodes are spaced along the lead such as to occupy a lead length of between about 20 mm and about 150 mm. Claim 102 adds the limitation that a distance between adjacent pairs of the electrodes is between about 5 mm to 30 mm. Claim 103 adds the limitation that the lead comprises a bend at the distal end, wherein the bend is at an angle between 30 degree to 90 degree.

In view of the above amendments and remarks it is respectfully submitted that claims 19, 41, 43-45, 74-78, 80, 82, 84, 86-103 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

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Respectfully submitted,



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**Encls:**

- Petition for Extension (1 Month)
- Request for Continued Examination (RCE)
- References: US Patent No. 4,773,433.